



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/500,225

09/03/2004

Katsutoshi Yoshizato

2004-0990A

7468

513

7590

02/06/2006

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,225	YOSHIZATO ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>25 June 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 22 November 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Medina et al (Biotechnology Techniques, 1997).

Medina et al teach the step of immobilizing *E. coli* O157:H7 cells on the surface of a BIAcore sensor chip (i.e. surface plasmon resonance analyzer) and performing binding interactions of the cells with anti-*E. coli* IgG (i.e. external stimulus) by injecting the IgG at a flowrate for a specific amount of time over the sensor surface and measuring a continuous, real-time response (i.e. physiological activity) before, during (i.e. primary signal), and after the injection period (i.e. secondary signal). See page 173, right column, 2nd paragraph to page 174, left column, 1st paragraph; and Figure 2 and caption.

Response to Arguments

4. On pages 4-5 of the response, filed 22 November 2005, Applicants argue that Medina reference fails to disclose or suggest the limitation of “measuring a secondary signal after elimination of the external stimulus”. See page 4, 6th paragraph. Applicants cite Medina as evaluating an antibody’s effect on bacterial cells by measuring a primary signal caused by specific binding of the antibody on the cells, but “never discloses or suggests measuring a secondary signal after a separation of the antibody from the cell.” See page 4, last paragraph.

Applicants’ arguments have been fully considered, but are not persuasive. It seems as if Applicants’ intend the limitation “measuring a secondary signal after elimination of the external stimulus” to mean that any specific binding substance (i.e. antibody) bound to the claimed cells must be physically removed from the cells before the claimed secondary signal can be measured. However, nowhere in the specification is there disclosure that the “elimination of the external stimulus” constitutes physical removal of a specific binding substance from the immobilized cells. In fact, the specification indicates the opposite, as described on page 4 and shown in Figure 1. The specification states that, in referring to Figure 1, “IL-2 was injected between T1 and T2” and that “The reaction between T1 and T2 indicates the primary signal, and the reaction after T2 the secondary signal”. See page 4, 2nd paragraph and Figure 1. Therefore, the specification provides support for the situation where the claimed primary signal is considered to be a measurement during the injection of an antibody (i.e. IL-2)

that specifically binds to cells, and the claimed secondary signal is considered to be a measurement after the injection has stopped, but without physical removal of the already bound antibodies.

Even if the specification had disclosed that specific binding substances must be physically removed before a second measurement can be taken, the claim language is broad enough to encompass the situation described in Figure 1. Since the term "external stimulus" is not defined in the specification, the term can be considered to be the flow of specific binding substances onto the cells. Elimination of the external stimulus would therefore indicate the elimination of the flow. Medina therefore fully anticipates the instant claim by teaching the measurement of binding before, during, and after injection of anti-E.coli IgG in an SPR device containing immobilized E.coli cells therein.

Conclusion

5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1641

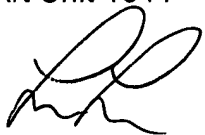
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y. Lum
Patent Examiner
Art Unit 1641



LYL


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/03/06